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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,220	10/15/2003	Xu Wu	021288-001820US	8079

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,220

Applicant(s)

WU ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-35, 42 and 44-46 is/are rejected.
- 7) ☒ Claim(s) 10 and 36-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/9/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

5.0

DETAILED ACTION

The Rejections over Montgomery, Imbach (1999), Basyouni, US 6255485, US 2002/0016329, and WO 200071543 A1 were overcome by the narrowing of the definition of R6.

Claims 1-3, 6-7, and 11-35, 42, 44-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A. The R^{4a} choice of C₃₋₈cycloalkyl is clearly new matter. Applicants point to species at pages 15, 17, 19 and similar species in claims 8-9. However, the material added to the claims is far broader than that for these reasons:

- a. These only provide cyclohexyl; the claim language is broader.**
- b. These only provide the ring attached to a methyl. The claim language allows the R^{4a} to be attached to ethyl propyl and butyl, as well as being attached to cycloalkyl, Hydroxyalkyl, aryl and aralkyl.**

B. The R^{4a} choice of aryl-C₀₋₂alkyl is clearly new matter. This would allow, for example, R⁴ to be cyclopropyl substituted by benzyl. There does not appear to be any language that would be embrative of this. Applicants point to claim 8, and to page 8, lines 1-7 of the specification. However:

- a. The specification is simply a definition of aralkyl. It doesn't say that R^{4a} can be aralkyl.**
- b. The claim 8 third choice is simply one choice, the phenoxy. The claim language is much broader, as it would cover other choices, e.g. phenethyl.**
- c. The choice is only on an aralkyl (a benzyl, to be specific). The new claim language would allow it to be on e.g. cyclopropyl.**

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d. Claim 8 is only in the specific context of a precise R1 choice, and a single R6 choice; the claim 1 is not so limited.

C. The R⁴ choice of aryl-C₀₋₃alkyl is clearly new matter; only 0-2 is permitted. Applicants point to claim 4 and 8-9, and to page 8, lines 1-7 of the specification. However:

a. The specification is simply a definition of aralkyl. It doesn't say that R⁴ itself can be aralkyl having 3 carbons in the alkyl.

b. Claim 8 is only in the specific context of a precise R1 choice, and a single R6 choice; the claim 1 is not so limited.

c. The reference to claim 4 is in error. It only has C2, not C3.

d. Further, the material in claim 8 is narrower. It has only the phenyl for aryl, whereas "aryl" is much broader, as it could be naphthyl or heteroaryl. Further, it has the aryl on the last carbon, but the new claim language could permit the aryl to be on the second or first carbon. In addition, the species listed in claim 8 has only the pure carbon chain, but the new claim language would permit the oxygen substitution. That is, the new claim language would permit e.g. phenoxyethyl.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 11-35, 42, 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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1. The commas must be removed from the formula. That is, something like N(A, B) should be written as N(AB) or N(A)(B). The traverse is unpersuasive. Commas are used sentences (but not in structural formula) to separate items of a list, but this is not a true list.. Either of the N(AB) or N(A)(B) formats are conventional and can be used.
2. In Heterocycle, such as is formed from R3, of what types? "Heterocyclic" is indefinite. What is the size of the ring? What is the number and nature of the heteroatoms? Can the ring be fused or spiroconnected to another ring, and if so, what kind of ring? Can the ring be bridged? Unsaturated? Cf. *In re Wiggins*, 179 USPQ 421, 423. The traverse is unpersuasive. Paragraph does not provide a "definition" as the remarks state, such a handful of examples. These cannot define a term. For example, none of these have S opr P as the heteroatom. Is one to infer that that rings with S and P are not included? None of these rings are aromatic; does one infer that aromatic rings are not intended?
3. The term "alkyl" has been rendered indefinite by the specification. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The meanings quoted by applicants are not the usual meaning at all. Alkyl is a group of the formula $-C_nH_{2n+1}$, as is set forth in such sources as Hack's Chemical Dictionary and Hawley's Condensed Chemical Dictionary, or any textbook of organic chemistry. As such it cannot be unsaturated, rings or have heteroatoms. Since both rings and unsaturation are permitted, groups like phenyl would be embraced. According to paragraph 0021, the term covers not only terms with unsaturation, and with rings, but also "heteroalkyl", a term which according to paragraph 0024 is broad enough to embrace choices like SCH_3 or OH. These are not alkyl groups. It appears that virtually anything other than H will fall into the definition of alkyl. The traverse is unpersuasive. How, exactly would one of ordinary skill in the art "recognize" that the term

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alkyl does not cover phenyl? The term has been so distorted from its normal meaning that the actual language of the specification permits the group to be things such as phenyl or OH.

Applicants cannot have it both ways. Applicants cannot argue that the correct meaning of the term will be overridden by the definition provided in the specification, but at the same time, some unknown principle will then override what the specification says to disqualify phenyl (applicants do not comment on whether SCH₃ or OH are embraced).

4. A similar problem occurs with aryl and heteroaryl. Judging from the first sentence of paragraph 0027, aryl does not have to be aromatic, and would cover a terms such as cyclooctadiene or dihydropyridine. These are not an aryl or heteroaryl choices under the normal meaning of the term. The traverse is unpersuasive. The same issue arises. Applicants says that one of ordinary skill in the art would somehow recognize that e.g. cyclooctadiene is not covered, but the plain language of the specification does in fact embrace it.

Claims 8-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most choices, does not reasonably provide enablement for the third choice in claim 8, the last two choices in claim 8, and the 6th to last choice in claim 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. These choices are not within Formula I, to which the utility is tied. Hence, these choices do not fall within the utility umbrella, and as a result, the specification does not teach how to use them. The reasons were given previously in detail, and the traverse is unpersuasive. Applicants have amended claim 1, but the problem was never with claim 1 in the first place, but rather, with a failure in the specification.

Claims 10, 36-41 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Specification

The abstract is objected to as too vague. Needed is the definitions for R6 and R4.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

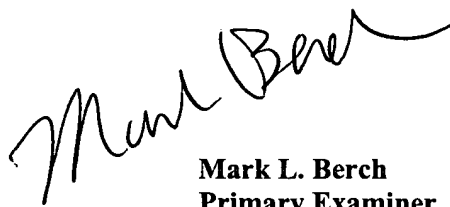
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Mark L. Berch". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

Mark L. Berch
Primary Examiner
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6/20/05